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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/687,483 10/13/00 KOSTER

H 24736-2033

HM22/0921  
STEPHANIE L. SEIDMAN, ESQ.  
HELLER EHRMAN WHITE & MCAULIFFE  
4350 LA JOLLA VILLAGE DRIVE  
SAN DIEGO CA 92122-1246

EXAMINER

HARTTER, A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/21/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. 09/687,483	Applicant(s) KOSTER ET AL.	
	Examiner Amy Hartter	Art Unit 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-100 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**Restriction/Election**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a plurality of samples, classified in class 424, subclass 520. Please choose one of the parameters from Claim 2 for a species election.
- II. Claim 4-17,30-31,43-54, and 98-99 drawn to producing a database, classified in class 702, subclass 19. Please choose one parameter from Claim 9 for a species election
- III. Claims 18-25, and 55 drawn to identifying polymorphisms in healthy subjects, classified in class 435, subclass 6.
- IV. Claims 26-29, and 97, drawn to a database that is comprised of a datapoint representative, classified in class 703, subclass 11.
- V. Claims 32-42, drawn to a system for high throughput processing of biological samples, classified in class 422, subclass 129.
- VI. Claim 56, drawn to identifying a polymorphism that is associated with mortality, classified in class 435, subclass 6.
- VII. Claims 57-59, drawn to the determination of the frequencies of genetic variations, classified in class 702, subclass 20. There are two specie

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elections in Claim 58. If this Group is elected, then one of the following species is also required. They are:

A. Variation type; claim 58, lines 2-4 therein

B. Bipolymer type; claim 58, lines 5-6 therein

VIII. Claims 60-64, drawn to a method of discovery of a polymorphism within a population via sorting a database, classified in class 702, subclass 19.

There are three species within Claim 62. If this Group is elected, then one of the following species is also required. They are:

A. Nucleotide glycolase

B. Nickase

C. Type II restriction enzyme

IX. Claims 65-70, drawn to a method of discovery of a polymorphism in a population via samples of body tissue or fluid, classified in class 435, subclass 6. There are also species in Claim 67. If this Group is elected, then one of the following species is also required. They are:

A. Nucleotide glycolase

B. Nickase

C. Type II restriction enzyme

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- X. Claims 71-80, drawn to the correlation of a polymorphism with a parameter, classified in class 702, subclass 19. Please select a parameter from Claim 72 for a species election.
- XI. Claims 81-82, drawn to haplotyping polymorphisms in a nucleic acid, classified in class 702, subclass 20.
- XII. Claims 83-85, drawn to haplotyping a polymorphisms in a population, classified in class 702, subclass 20.
- XIII. Claims 86-87, drawn to detecting methylated nucleotides within a nucleic acid sample, classified in class 435, subclass 6.
- XIV. Claims 88-95, drawn to a method of identifying a biological sample, classified in class 702, subclass 19. There are also species of biological sample contents. If this Group is elected, then one of the following species is also required. They are:
  - A. nucleic acid
  - B. Protein data
  - C. Other specific biopolymer or enzyme type.
- XV. Claim 96, drawn to a subcollection of samples from a target population, classified in class 424, subclass 520.
- XVI. Claim 100, drawn to a system for the processing of biological samples, classified in class 422, subclass 50.

### **Detailed Action**

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups XV and I are of the nature of a product and are thus separate and distinct from the process inventions as defined by the following paragraph.

The inventions of I and XV and II-XIV and XVI are related as product and processes of use. The inventions can be shown to be distinct if either of both of the following can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of the samples that are collected in Groups I and XV could be used in alternative testing procedures and do not have to be applied to the processes that are mentioned in the instant application. Such processes could include cancer testing or other alternate testing.

In the cases of the products in Groups I and XV, the difference in the product lies in the fact that in Group I a mass spectrometer and a throughput processing of biological samples is not employed and in Group XV these tactics are employed. This would yield different products in the two Groups and thus make them separate and distinct.

Groups II-XIV differ in the tactics employed in the identification of the defined target and the definition of that target. These Groups have the varying target of polymorphisms; an extended primer, genotype data, and the methods vary from the use

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of a mass spectrometer, high throughput biological processing, and the use of a data analysis system. The targets or products in the instant case can be used for the production of cDNA in the case of the primers and the genotype data can be used in identifying alternate diseases.

Because these inventions are distinct for the reasons give above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes is proper.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from this examiner should be directed to Amy Hartter whose telephone number is (703) 305-1696. The examiner can normally be reached M-F from 8:00 to 4:30 p.m. (Eastern Time).

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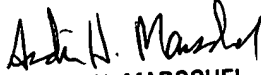
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 305-4028.

The fax phone numbers for the group are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature relating to the status of this application should be directed to the Patent Analyst, Kim Davis, whose telephone number is (703) 305-3015 or to the Technical Center Receptionist whose telephone number is (703) 305-0196.

  
Amy Hartter

(703) 305-1696

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER